510(k) SUMMARY

JUL 30 2012

Submitter	Safe Orthopaedics Parc des Bellevues Allée R. Luxembourg - Le Californie 95610 Eragny sur Oise - France
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Trade Name	SteriSpine™PS
Common Name Classification Name	Pedicle screw spinal system
Product code	MNI. MNH. KWP. NKB
CFR section	888.3070
Legally marketed predicate device	STERISPINE PS PEDICLE SCREW K112453 Manufactured by SAFE ORTHOPAEDICS
SPECIAL 510k	Modification to STERISPINE PS PEDICLE SCREW (Extension of range of products)

Description:
SteriSpine™PS system includes Pedicle Screw and Rod. Components of SteriSpine™PS systems are made of Titanium Ta6V Eli grade conforming to ASTM F136.
SteriSpine™PS components are supplied sterile with a single-use set of surgical instruments. The components added within this submission include:

- New references of Pedicle screws,
- New references of Straight Rods,
- New references of Rods, compatible with a new Rod holder
- 3 Instruments :
  - Open Screw Extender PSANC024,
  - Open Set Screw Guide PSANC022,
  - Rod Holder PSANC025.

Indications for use:
The SteriSpine™PS system is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion.
SteriSpine™PS System is intended for posterior, non cervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e.. fracture or dislocation); spinal stenosis; tumor; pseudoarthrosis; and failed previous fusion.

Performance data:
SteriSpine™PS conforms to special control established for Pedicle screw spinal system and to « Spinal System 510(k)s - Guidance for Industry and FDA Staff Document » issued on: May 3. 2004.

Mechanical testing was conducted per ASTM F1717 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model and ASTM F1798 Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants. Testing according to ASTM F1717 includes Static Compression, Static

Torsion and Dynamic Compression. Testing according to ASTM F1798 includes Static slipping, Static bending and Static rotation. Results demonstrate comparable mechanical properties to the predicate device. Cadaver testing performed to validate the instrumentation have been presented. No additional testing has been performed for the added components.
Clinical data from a review of the literature has been presented in the class III summary.

Substantial equivalence:
SteriSpine™PS system is substantially equivalent to its predicate devices in terms of intended use, material, design, mechanical properties and function.
Non clinical performance testing according to special control demonstrate that SteriSpine™PS is as safe, as effective, and performs as safely and effectively as its predicate devices.

2012. April 27th

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 30 2012

Safe Orthopaedics
% Mr. Pierre Dumouchel
Parc des Bellevues
Allee R.Luxembourg- Le Californie
95610 Eragny sur Oise - France

Re: K121299
Trade/Device Name: SteriSpine™ PS
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI, KWP
Dated: July 03, 2012
Received: July 03, 2012

Dear Mr. Dumouchel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K121299

Device Name: SteriSpine™PS

Indications for Use:

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SteriSpine™PS System is intended for posterior, non cervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e.. fracture or dislocation); spinal stenosis; tumor; pseudoarthrosis; and failed previous fusion.

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH. Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121299